Ann. Occup. Hyg., Vol. 53, No. 5, p. 549, 2009

Letter to the Editor

NIOSH Definition of Closed-System Drug-Transfer Devices

Received 18 March 2009; in final form 6 April 2009; published online 27 May 2009

Following publication of our paper on a double-filter system for preparing drugs (Nygren *et al.*, 2008), we have received some comments on the Results and discussion section, where the tested system is compared with other devices in relations to the National Institute for Occupational Safety and Health (NIOSH) definition of a closed system.

The discussion refers to how the NIOSH definitions (NIOSH, 2004) should be interpreted and how different drug-transfer devices comply with the definition. The NIOSH definitions are as follows:

> Closed system drug-transfer device (CSTD): a drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system.
>
> Closed system: a device that does not exchange unfiltered air or contaminants with the adjacent environment.

In our paper, we interpreted the NIOSH definition of CSTD as requiring a physical barrier mechanically preventing any exchange between the interior of the system and the outside environment. The discussion in the paragraph was based on that interpretation.

After publication of their Alert (NIOSH, 2004), NIOSH clarified their opinion in a letter to Carmel Pharma ab (Göteborg, Sweden) (Thomas H. Connor, NIOSH Cincinnati, personal communication). They stated:

In regards to your question on what NIOSH considers to be a closed-system transfer device (CSTD), the Alert's glossary was not really intended to be a specification guide for equipment design criteria. Rather, we sought to identify the desired function that the defined piece of equipment should provide. In the case of the CSTD, the intended function was to preserve the sterility of the product while preventing the escape of a hazardous drug, in whatever form it may exist, into the surrounding environment. In that regard, if a hypothetical CSTD was successful in meeting these performance criteria during the drug transfers for which it was intended, we would probably consider it as meeting the definition. If however, the hazardous drug under manipulation included a vapor component or could change phase to vapor during the drug transfer process, leading to escape of drug from the system, then that system would fail to meet the intended function of our definition.

We agree that this clarification is sensible. A definition of this kind should be a performance criterion rather than a design or construction criterion. One of the problems with a definition that is not clearly based on performance criteria but rather implies a specific construction or design is that such definition will exclude other technical solutions with the same or better performance according to the specified criteria.

In conclusion, compound systems, like the ones we had studied, should all be regarded as meeting the NIOSH CSTD definition, if they are shown to perform according to the specified performance criteria.

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doi:10.1093/annhyg/mep030